TLC Trial Form ADE.04
Adverse Drug Experience Case Report Form

Center ID:	___ - ___
Study ID:	T___ ___ ___ ___ - ___

Send to:
TLC Data Coordinating Center

INSTRUCTIONS: *This form is to be filled out when there has been a serious **and** unexepected adverse drug experience. For the purposes of the TLC Trial, any event which results in inpatient hospitalization or death during the treatment phase is considered a serious and unexpected adverse drug experience, even if thought to be unrelated to study drug. The TLC Form ADECHK, documenting reporting procedures, should also be filled out. If this ADE was immediately life-threatening or resulted in death, the TLC physician must notify the FDA by phone within three working days.*

BACKGROUND INFORMATION

1. **Gender** ( )$_0$ Boy ( )$_1$ Girl

2. **Date of Birth** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

ADVERSE EXPERIENCE

3. **Case report status** ( )$_1$ New case ( )$_2$ Follow-up report

4. **Date of onset** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

5. **Inpatient hospitalization** ( )$_0$ No ( )$_1$ Yes

   a. **Date admitted** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

   b. **Date discharged** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy* ( )$_1$ Still in hospital as of this report

   c. **Hospital**

   _____
   Name of hospital

   _____
   Address

   _____
   City State and Zip

6. **Date resolved** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy* ( )$_1$ Unresolved as of this report

7. **Life threatening** ( )$_0$ No ( )$_1$ Yes

8. **Fatal** ( )$_0$ No ( )$_1$ Yes

   a. **Date of death** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

If this ADE was life-threatening or fatal, the TLC physician must notify the FDA by phone within the next three working days.

9. Describe the events surrounding this ADE. Record all pertinent details, including concomitant medications, intercurrent events, and duration if less than 24 hours.

Center ID:	____ - ____
Study ID:	T____ ____ ____ ____ - ____

STUDY DRUG

10. **Treatment status**
( )$_1$ Round 1
( )$_2$ Round 2
( )$_3$ Round 3
( )$_4$ Followup

If this child was in treatment phase at time of this event:

11. **Date started drug** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

12. **Dosage**
a. **Days 1 to 7** ____ - ____ - ____

b. **Days 8 to 26** ____ - ____

13. **Date stopped drug** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy* ( )$_1$ Still taking study drug

14. As a result of this ADE, were any changes made in the administration of TLC Study drug?

( )$_1$ No change in administration of Study drug
( )$_2$ Study drug discontinued permanently
( )$_3$ Study drug interrupted and restarted
( )$_4$ Other, *specify:* _____

OUTCOME

15. In the opinion of the TLC physician, was this ADE related to TLC Study drug?

( )$_1$ Related
( )$_2$ Possibly related
( )$_3$ Not related
( )$_4$ Not known

16. Was this ADE the result of overdose?

( )$_0$ No ( )$_1$ Yes

17. Was this ADE permanently disabling?

( )$_0$ No ( )$_1$ Yes

18. Has this child suffered any permanent damage as a result of this ADE?

( )$_0$ No ( )$_1$ Yes

19. Did this child require prolonged hospitalization as a result of this ADE?

( )$_0$ No ( )$_1$ Yes

20. Did this ADE cause cancer?

( )$_0$ No ( )$_1$ Yes

ADMINISTRATIVE MATTERS

21. **Date** ____ ____ / ____ ____ / ____ ____ *mm/dd/yy*

22. **TLC Physician** _____ ___ - ___ ___ ___ ___
Signature *TLC code*

COMMENTS

For DCC use only

( )$_A$ Succimer ( )$_P$ Placebo